ICD

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,779	06/21/2001	Chandran R. Sabanayagam	701586/50113-C	6933

26248 7590 07/14/2004

NIXON PEABODY LLP
101 FEDERAL ST
BOSTON, MA 02110

EXAMINER	
LU, FRANK WEI MIN	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/886,779	SABANAYAGAM ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 23-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11 and 23-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/1/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on March 12, 2004 has been entered. The claims pending in this application are claims 11 and 23-38. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 11 and 23-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.*, (US Patent No. 5,753,439, filed on May 19, 2003).

Smith et al., teach arrays of probes. Each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region wherein the variable region comprised one or more repeat sequences. The repeat sequences comprise heterologous or homologous sequences which are variable in length or base sequences. Sequences contain purine or pyrimidine bases or neutral bases such as inosine. Either the nucleic acids or the probes of the array are labeled with a detectable label or fixed to a solid support. Probes are single-stranded or partly single-stranded and partly double-stranded. Arrays comprise between about 10 to about

10,000 different probes (see column 9, lines 18-34). In certain situation, the repeat sequences are about 2 to about 2000 (see column 15, claims 1 and 2).

Regarding claims 11 and 23, since claims 11 and 23 are directed to a product (an ordered redundant array of immobilized oligonucleotides) and are not directed to a method, the method steps recited in claims 11 and 23 which are used to make the ordered redundant array of immobilized oligonucleotides are no patentable weight and claims 11 and 23 are product-by-process claims. Note that it is well established that even though product-by process claims are limited by and defined by the process, the determination of the patentability of the product is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.". *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). Since claims 11 and 23 are directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate while Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, disclose an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) as recited in claims 11 and 23. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end

has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claim 30, claim 30 is directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate and each sequence of interest is different for each extended immobilized oligonucleotide. Since Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2), Smith *et al.*, teach an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) comprises at least two copies of sequence of interest (ie., repeats) and each sequence of interest (ie., each of repeat sequences) is different and can bind to a different target nucleic acid. The probes on the array taught by Smith *et al.*, are considered to be along the Z coordinate since each of these probes from one end to another end has 5' to 3' direction. Furthermore, applicant has no evidence to indicate that these probes on the array taught by Smith *et al.*, are not along the Z coordinate.

Regarding claims 24-29 and 31-33, since these different probes taught by Smith *et al.*, have 2-2000 repeats (see column 9, lines 18-34 and column 15, claims 1 and 2), claims 24-29 and 31-33 are anticipated by Smith *et al.*.

Regarding claims 34-38, different probes on the arrays in Figures 6A to 6C taught by Smith *et al.*, have 10-109 repeats wherein 5' and 3' ends of these probes are labeled with biotin

and rhodamine respectively. Target nucleic acids comprising 88, 55, and 17 repeats with a fluorescein at their 3' ends are hybridized with an identical array in separate experiments and digested with S1 nuclease. Then strand displacement assays are performed. When the probe contains more internal repeats than the target, the rhodamine label is lost in the strand displacement and the resultant product is red. Similarly, when the target contains more internal repeats than the probe, the fluorescein label is lost and the product is green. When the probe and the target both contain the same number of repeats, both rhodamine and fluorescein remain and the resultant color is yellow (see column 12, example 4, and Figures 6A to 6C). When target nucleic acids comprising 88, 55, and 17 repeats hybridize with their corresponding probes (having 88, 55, and 17 repeats) on the array, the resultant colors must be yellow. Therefore, Smith *et al.*, teach that at least two copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claims 34 and 35, at least ten copies of a fragment of a template nucleic acid (ie., 88, 55, or 17 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeats of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 37, and at least fifty copies of a fragment of a template nucleic acid (ie., 88 or 55 repeats in one of the target nucleic acids) corresponding to the sequence of interest (ie, repeat of the probes on the array) are hybridized to at least one of the extended immobilized oligonucleotides comprising the sequence of interest along the z coordinate as recited in claim 38.

Therefore, Smith *et al.*, teach all limitations recited in claims 11 and 23-38.

Response to Arguments

In page 7, last paragraph bridging to page 8, third paragraph of applicant's remarks, applicant argues that "[U]nlike the probes of Smith, the probes of the present claims do not require a constant 3' region which binds the 5' end of the target nucleic acid. Consequently, **each probe** of the present array is capable of **binding at least two target nucleic acids,** while occupying only one spot in the x/y dimension (see, Figure IB and Figure 2B, Appendix A). Preferably, each probe binds multiple target nucleic acids along the z coordinate. For example, when there are 10 repeats, there can be ten target nucleic acids, when there are fifty repeats, there can be 50 bound target nucleic acids along the z coordinate. Whereas with the Smith array, the 5' end of the probe and the 3' end of the probe must bind to the target nucleic acid. Accordingly, it is clear only one target nucleic acid can bind to each probe. Thus there is no anticipation (see particularly claims 34-38). It is this multiplication of the target sequence in the z-dimension allowing the almost limitless extension of the immobilized probe in the z-dimension, that clearly differentiates the arrays of the present invention from the arrays of Smith".

This argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, claim 11 or 23 is directed to an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate while claim 30 is directed an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z

coordinate and each sequence of interest is different for each extended immobilized oligonucleotide. Since Smith *et al.*, teach an array comprising 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2) and wherein the probes on the array are considered to be along the Z coordinate because each of these probes from one end to another end has 5' to 3' direction, Smith *et al.*, disclose an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) as recited in claims 11 and 23, and an ordered redundant array of extended immobilized oligonucleotides wherein each extended immobilized oligonucleotide comprises at least two copies of sequence of interest along the z coordinate (ie., each of 10 to 10,000 different probes with 2-2000 repeats wherein the repeat sequences comprise heterologous sequences which are variable in length or base sequence) and each sequence of interest (ie., each of repeat sequences) is different for each extended immobilized oligonucleotide. Second, although applicant argues that "each probe binds multiple target nucleic acids along the z coordinate. For example, when there are 10 repeats, there can be ten target nucleic acids, when there are fifty repeats, there can be 50 bound target nucleic acids along the z coordinate. Whereas with the Smith array, the 5' end of the probe and the 3' end of the probe must bind to the target nucleic acid", since Smith *et al.*, teach that each probe in the array comprises a constant 5'-region, a constant 3'-region and a variable internal region with 2-2000 repeats wherein the repeat sequences comprise heterologous

sequences which are variable in length or base sequence (see column 9, lines 18-34 and column 15, claims 1 and 2), the variable internal region of each probe on the array taught by Smith *et al.*, is capable of binding 2-2000 target nucleic acids or fragments thereof. Therefore, "only one target nucleic acid can bind to each probe" argued by applicant is incorrect. Furthermore, applicant has no evidence to show that 5' and 3' of one probe on the arrays taught by Smith *et al.*, must bind to an identical target nucleic acid. Third, the phrase "the target sequence in the Z-dimensional allowing the almost limitless extension of the immobilized probe in the z-dimension" argued by applicant is not in the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Fourth, related appendix A, the claims do not require that each of the extended immobilized oligonucleotides does not contain a constant 3' region.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. No claim is allowed.

6. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703)872-9306 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
June 30, 2004

FRANK LU
PATENT EXAMINER